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PTO/SB/08A (08-03)
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1623

Complete if Known

Application Number 10/759,985

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

Complete if Known

Application Number 10/759,985

Filing Date January 16, 2004

First Named Inventor Schinazi et al.

Group Art Unit

(use as many sheets as necessary)

Examiner Crane, Lawrence E.

Sheet 1 of 14 Attorney Docket Number 18085 105326 FMTI

18085.105326 EMU 133 CON 5

				U.S. PATENT DOCUMENTS		
Examiner Initials *	Cite No. 1		ument Kind Code if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pgs, Clims, Lns, Where Relevant Passages/Relevant Figs Appear
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Examiner Signature L. E. Crane Date Considered 01/02/2008

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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C	ubmitted for form 1449/PTO			Complete if Known			
Submitted for form 1449/PTO				Application Number	10/759,985		
	INFORMATION	DISCLOSE	TRE.	Filing Date	January 16, 2004		
STATEMENT BY APPLICANT				First Named Inventor	Schinazi et al.		
•				Group Art Unit	1623		
			•	Examiner Name	Crane, Lawrence E.		
Sheet	2	of	14	Attorney Docket Number	18085.105326 EMU 133 CON 5		
				•	4742181 1.DO		

				U.S. PATENT DOCUMENTS		4742101_1.DO
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Docu Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pgs, Clims, Lis, Where Relevant Passages/Relevant Figs Appear
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2	BY	EP	0 206 497	B1	Wellcome Foundation LTD	07-20-1994		T
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	Examiner Signature	L. E. Crane	Mean	Date Considered	01/02/2008

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IN	FORMATIO	N DISCLOSU	<b>IRE</b>	Filing Date	January 16, 2004		
	TATEMENT I			First Named Inventor	Schinazi et al.		
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Sheet 3 of 14				Attorney Docket Number	18085.105326 EMU 133 CON 5		

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				FORE	IGN PATENT DOCUMENTS		4742181_1.	
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I	NFORMATION	N DISCLOSI	URE.	Filing Date	January 16, 2004		
	STATEMENT B			First Named Inventor	Schinazi et al.		
				Group Art Unit	1623		
				Examiner Name	Crane, Lawrence E.		
Sheet	4	of	. 14	Attorney Docket Number	18085.105326 EMU 133 CON 5		

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Examiner	Cite	For	eign Patent Docum	ent	Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines,	Т.
Initials * No. 1		Office <sup>3</sup>	Number Kind ( (if know		of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	
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2	DB	wo	94/14831	A1	University of Alberta	07-07-1994		†
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Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
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Examiner Signature	L. E. Crane	Mr. Com	Date Considered	01/02/2008

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\*\*\*, Dinlicate citations - see PTO-892 for original citates;
Unique citation designation number. \*See attached Kinds of U.S. Patent Documents. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

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Submitted for form 1449/P1O		Application Number	10/759,985	
INFORMATION DISCLOS	SURE	Filing Date	January 16, 2004	
STATEMENT BY APPLIC		First Named Inventor	Schinazi et al.	
		Group Art Unit	1623	
		Examiner Name	Crane, Lawrence E.	
Sheet 5 of	14	Attorney Docket Number	18085.105326 EMU 133 CON 5	

4742181 1.DOC OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, Cite symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. Initials ' No.1 BALZARINI et al., "5-Chloro-substituted Derivatives of 2', 3'-Didehydro-2', 3'-dideoxyuridine, 3-EA Fluoro-2', 3'-dideoxyuridine and 3'-Azido-2', 3'-dideoxyuridine as Anti-HIV Agents," Biochem. Pharmacology, 38(6), 869-874 (1989). BALZARINI, J., et al., "Potent and Selective Anti-HTLV-III/LAV Activity of 2',3'-Dideoxycytidinene, EB the 2',3'-Unsaturated Derivative of 2',3'-Dideoxycytidine," Biochemical and Biophysical Research Communications, 140(2):735-742 (1986). BEACH, J. W., et al., "Synthesis of Enantiomerically Pure (2'R,5'S)-(1)-[2-hydroxymethyl)-oxatiolan-5yl] Cytosine as a Potent Antiviral Agent Against Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)," J. Org. Chem., 57:2217-2219 (1992). BELLEAU, B., et al., "Design and Activity of a Novel Class of Nucleoside Analogs Effective Against HIV-1," International Conference on AIDS, Montreal, Quebec, Canada, Jun. 4-9, 1989, p. 516. EE BELLEAU, B., et al., Chem. Abst. 118(17):169533s (1993). BELLEAU, B., et al., "A Novel Class of 1,3-Oxathiolane Nucleoside Analogs Having Potent Anti-HIV EF Activity," Bioorgan. Med. Chem. Lett., 3(8):1723-1728 (1993) BIRON et al., "Anti-HIV Activity of the Combination of Didanosine and Hydroxyurea in HIV-1 Infected Individuals," J. AIDS and Human Retrovirology, 10(1):36-40 (August 1995). BORTHWICK, et al., "Synthesis and Enzymatic Resolution of Carbocyclic 2'-Ara-Fluoro-Guanosine: A EH Potent New Anti-Herpetic Agent," J. Chem. Soc. Commun., 10:656-658 (1988). BOUFFARD, D.Y., et al., "Kinetic Studies on 2'2'-Difluorodeoxycytidine(Gemcitabine) with Purified ΕI Human Deoxycytidine Kinase and Cytidine Deaminase," Biochem. Pharmacol., 45(9):1857-1861 CARTER et al., "Activities of (-)-Carbovir and 3'-Azido-3'-Deoxythymidine Against Human EJ Immunodeficiency Virus In Vitro," Antimicrobial Agents and Chemotherapy, 34(6):1297-1300 (1990). CHANG, C.-N., et al., "Biochemical Pharmacology of (+) and (-)-2',3'-Dideoxy-3'-Thiacytidine as Anti-Hepatitis B Virus Agents", J. Biol. Chem., 267(3):22414-22420 (1992). CHANG, Chien-Neng, et al., "Deoxycytidine Deaminase-resistant Steroisomer Is the Active Form of EL (+/-)-2',3'-Dideoxy-3'-thiacytidine in the Inhibition of Hepatitis B Virus Replication," J. Biological Chemistry, 267(20):13938-13942 (1992). EM CHANG, Chungming, et al., "Production of Hepatitis B Virus In Vitro by Transient Expression of Cloned HBV DNA in a Hepatoma Cell Line," EMBO Journal, 6(3):675-680 (1987). EN CHEN, Chin-Ho, et al., "Delayed Cytotoxicity and Selective Loss of Mitochondrial DNA in Cells Treated with the Anti-Human Immunodeficiency Virus Compound 2',3'-Dideoxycytidine," J. Biological Chemistry, 264(20):11934-11937 (1989).

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	INFORMATION I	DISCLOS	SURE	Filing Date	January 16, 2004
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				Examiner Name	Crane, Lawrence E.
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	INFORMATION DISCLOSURE			Filing Date	January 16, 2004
	STATEMENT BY APPLICANT		First Named Inventor	Schinazi et al.	
				Group Art Unit	1623
				Examiner Name	Crane, Lawrence E.
Sheet	7	of	14	Attorney Docket Number	18085.105326 EMU 133 CON 5
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				Examiner Name	Crane, Lawrence E.	
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STATEMENT BY APPLICANT	First Named Inventor	Schinazi et al.
	Group Art Unit	1623
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Sheet 9 of 14	Attorney Docket Number	18085.105326 EMU 133 CON 5

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Me	IA	KIM et al., "Asymmetric Synthesis of 1,3-Dioxolane-Pyrimidine Nucleosides and heir Anti-HIV Activity," J. Med. Chem., 35(11):1987-1995 (1992).	
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				Examiner Name	Crane, Lawrence E.	
Sheet 11 of 14		14	Attorney Docket Number	18085.105326 EMU 133 CON 5		

4742181 1.DOC OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. Examiner Initials \* No.1 KA PAI et al., "Inhibition of Hepatitis B Virus by a Novel L-Nucleoside, 2'-Fluoro-5-Methyl-.beta.-L-Arabinofuranosyl Uracil," Antimicrob. Agents and Chemother., 40(2):380-386 (February 1996). KB PAINTER et al., Chem. Abst. 117(23):226298z (December 7, 1992). KC PAINTER et al., Chem. Abst. 118(6):45750r (1992). PARKER et al., "Mechanism of Inhibition of Human Immunodeficiency Virus Type 1 Reverse Transcriptase and Human DNA Polymerase .alpha., .beta.0 and .gamma. by the 5'-Triphosphates of Carbovir. 3'-Azdo-3'-deoxythymidine. 2',3'-Dideoxyguanosine, and 3'-Deoxythymidine," J. Biological Chem., 208(3), 1754-1762 (January 25, 1991). KE PHILPOTT et al., "Evaluation of 9-(2-phophonylmethoxyethyl) adenine therapy for feline immunodeficiency virus using a quantitative polymerase chain reaction," Vet. Immunol. and Immunopathol., 35:155-166 (1992). PIRKLE and POCHANSKY, "Chiral Stationary Phases for the Direct LC Separation of Enantiomers," KF Advances in Chromatography, Giddings, J.C., Grushka, E., Brown, P.R., eds.: Marcel Dekker: New York, 1987; vol. 27, Chap. 3, pp. 73-127. KG RICHMAN, D. D., "The Toxicity of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex," N. Eng. J. Med., 317(4):192-197 (July 23, 1987). KH ROBINS et al., "Purine Nucleosides. XXIX. The Synthesis of 2'-Deoxy-L-adenosine and 2'-Deoxy-Lguanosine and Their Alpha Anomers," J. Org. Chem., 87:636-639 (March 1970). Van ROEY et al., "Absolute Configuration of the Antiviral Agent (-)-cis-5-Fluoro-1-[2-(Hydroxymethyl)-1,3-Oxathiolan-5-yl] Cytosine," Antiviral Agents and Chemotherapy, 4(6), 369-375 SATSUMABAYASHI, S. et al., "The Synthesis of 1,3-Oxathiolane-5-one Derivatives," Bull. Chem. KJ Soc. Japan, 45:913-915 (March 1972). SCHINAZI, R.F., et al., "Antiviral Drug Resistance Mutations in Human Immunodeficiency Virus Type KK 1 Reverse Transcriptase Occur in Specific RNA Structural Regions," Antimicrobial Agents and Chemotherapy, 38(2):268-274 (February 1994). KL SCHINAZI, R.F., et al., "Characterization of Human Immunodeficiency Viruses Resistant to Oxathiolane-Cytosine Nucleosides," Antimicrobial Agents and Chemotherapy, 37(4):875-881 (April KM SCHINAZI, R.F., et al., "Pure Nucleoside Enantiomers of .beta.-2',3'-Dideoxycytidine Analogs Are Selective Inhibitors of Hepatitis B Virus In Vitro," Antimicrobial Agents and Chemotherapy, 38(9):2172-2174 (Septmeber 1994).

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	STATEMENT B			First Named Inventor Schinazi et al.		
				Group Art Unit	1623	
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Sheet	12 of 14		14	Attorney Docket Number	18085.105326 EMU 133 CON 5	

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	Re	LA	SCHINAZI, R.F., et al., "Activities of the Four Optical Isomers of 2',3'-Dideoxy-3'-Thiacytidine (BCH-189) against Human Immunodeficiency Virus Type 1 in Human Lymphocytes," Antimicrobial Agents and Chemotherapy, 36(3):672-676 (March 1992).	
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he	NA	YOKOTA et al., "Comparative Activities of Several Nucleoside Analogs Against Duck Hepatitis B Virus In Vitro," Antimicrobial Agents and Chemotherapy, 34(7):1326-1330 (July 1990).	
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